2019 ANNUAL MEETING

December 5 | Gaylord National Harbor, MD

Didi Davis
VP, Informatics, Conformance & Interoperability
The Sequoia Project

eHealth Exchange

Content Remediation – Agenda

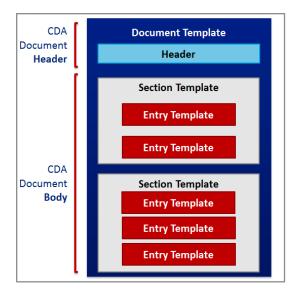


- 1. Content Testing Program Background & History
- 2. Value Set Authority Center (VSAC) Tips for Value Sets
- 3. Comparison of Existing Industry Content Testing Tools
- 4. Current Content Testing Program Status
- 5. Data Quality Challenges and Impact
- 6. Identify how best to remediate content errors and
 - How to understand the testing report
 - Understand how to report feedback for Issues/questions found in the tooling reports
 - How to leverage the the model-based validation report versus the scorecard
- 7. Display Tooling Support (XML and Stylesheet Formatting)

Content Testing Program Background & History



- 1. 06/2015 Testing Workgroup approved by the eHealth Exchange Coordinating Committee (CC)
- 2. 07/2016 Content Testing Pilot Completed
- 3. 01/2017 Requirements Effective
 - MU 2011 Edition (HL7 CCD/C32)
 - MU 2014 Edition (HL7 C-CDA R1.1) + Companion Guide
 - MU 2015 Edition (HL7 C-CDA R2.1) + Companion Guide

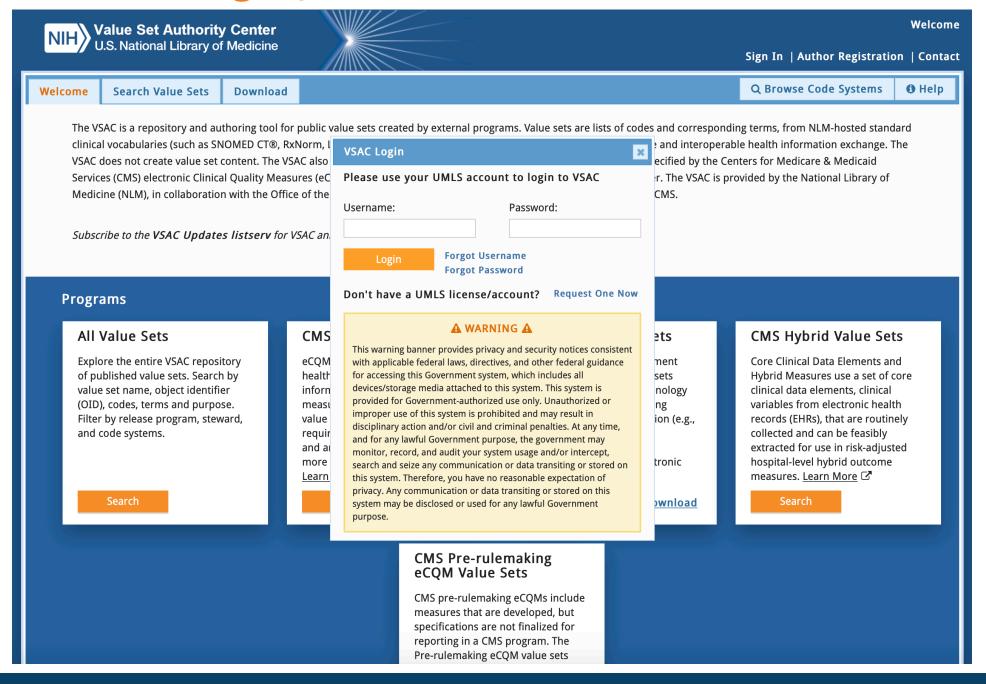


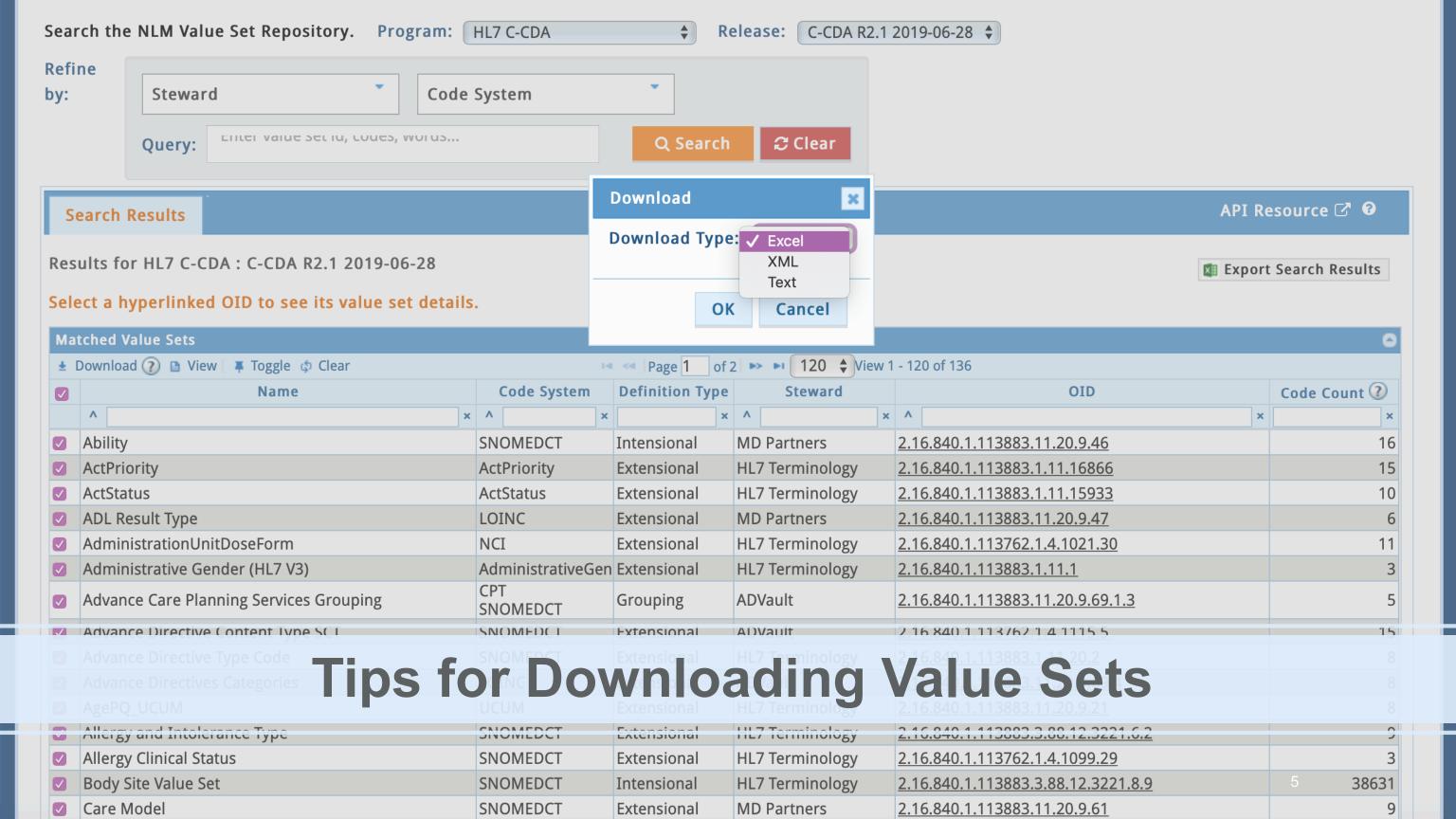
- 4. 02/2018 Sequoia Interoperability Testing Platform Launched/Available Content
- 5. 10/2019 All Existing and New Participants MUST Complete Initial Testing
- 6. 06/2021 All Participants have 18 months to remediate Reported Errors
 - Participants unable to remediate all errors and conformance issues should submit a remediation plan and/or a conformance waiver request to the eHealth Exchange for Coordinating Committee consideration within 16 months

Value Sets https://vsac.nlm.nih.gov/

Requires UMLS license/account







Comparison of Existing Industry Content Testing Tools



ONC SITE

(https://sitenv.org/sandbox-ccda)

- Open Source/API Available
- Limited Document Types, Section types and entries
- Value Sets from 06/2018
- Errata Updates Release Notes
- Does not store testing report
- Incorporates Scorecard Rubrics

Sequoia Interoperability Testing Platform (ITP)

(https://gazellecontent.sequoiaproject.org/EVSClient/home.seam?cid=368

- Open Source/API Available
- Validates all document types including C32, HL7 C-CDA R1.1 & R2.1
- Value Sets from 06/2019
- Errata Updates current 06/2019
- Permanent Link testing report storage
- Missing Scorecard Rubrics

Content Testing Status

- 15 or 5% of Eligible Participants organizations have <u>Passed</u>
 - https://ehealthexchange.org/participants/



- 95% have Submitted and <u>Failed</u> for various reasons, the most common are:
 - Vocabulary issues such as incorrect code system reference or incorrect value from value set referenced in the Value Set Authority Center (VSAC)
 - Required fields missing such as Street Address or other required CCDS data classes US Realm Header Requirements
- >7000 Documents Tested with >70% tested against HL7 C-CDA R2.1 Standards
- No known defects in the tooling at the present time
 - Issues as they are identified will be documented on the tooling home screen
 - Validators were last rebuilt and tested 11/29/2019
- Sequoia working with Vendors and their Customers to coordinate remediation

Industry-wide Content Pain Points





Optionality:

More than one way to do things and inconsistent implementations across vendors



Inconsistent terminology usage



Specification Ambiguity

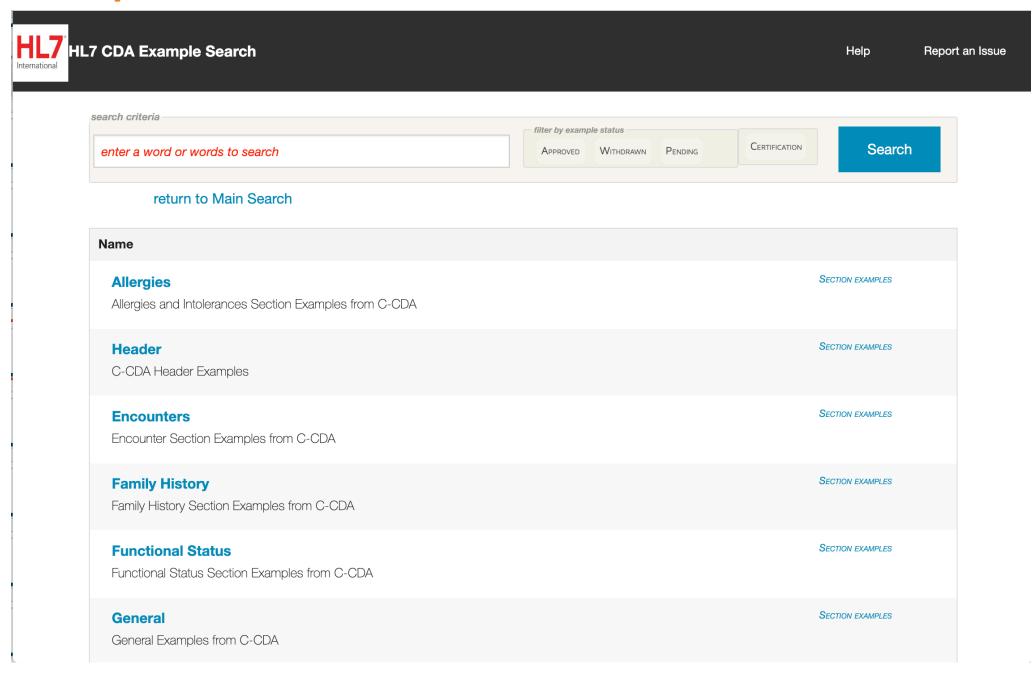


Complexity:

The C-CDA standard is difficult to understand and consume and is lacking in clearly documented examples

HL7 CDA Example Search





Data Quality Challenges and Impact



- How do you interface computers and humans in the medical environment?
 - Computers "think" structured and encoded data
 - Humans "think" in sentences, paragraphs, concepts
- Data Quality challenges and related clinical workflow of the systems used
 - Data Capture, Data Storage, Data Exchange
 - Transitions of Care (ToC) is a common occurrence that if improved, benefits the patient population Encounter based documents should be supported/exchanged
 - ✓ Consistent data representation and interpretation is necessary
 - ✓ Semantic Interoperable Exchange of the data captured and stored
 - ✓ C-CDA and FHIR is the US/ONC recommended mechanism for TOC TEFCA/USCDI

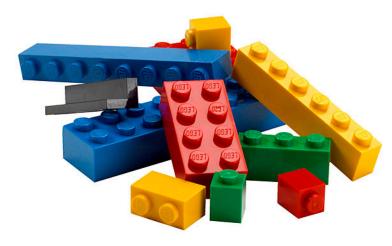
C-CDA R1.1 (9 Types) and R2.1 Document Types (14 Total)



11

C-CDA R1.0/R1.1

- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document



New as of C-CDA R2.0/R2.1

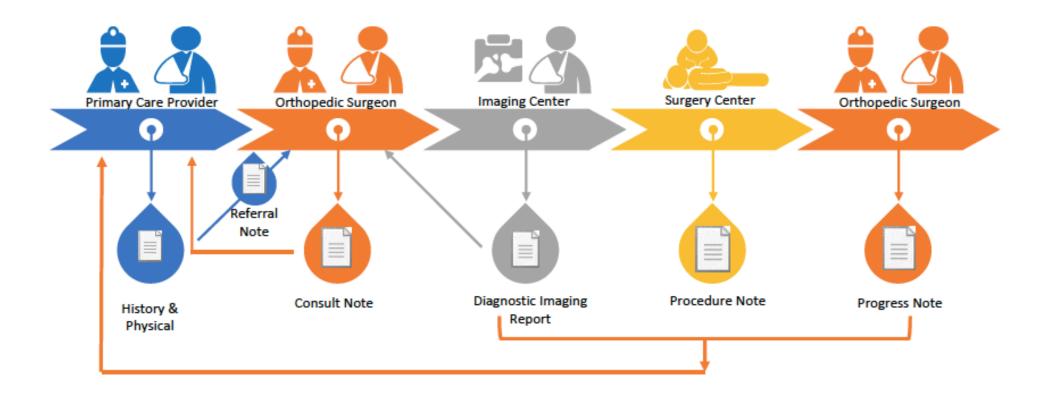
- Care Plan
- Referral Note
- Transfer Summary
- Clinical Note
- Patient Generated Summary

C-CDA: Exchanging the Patient's Story



12

- Today, most of the clinical data exchanged by systems leverages ONLY the CCD
- Many documents are not created by a human but by a machine on demand when queried. Data should be exchanged using appropriate document types.



Transfer Summary



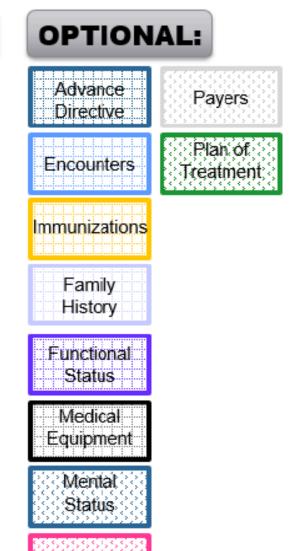
eHealth Exchange

13



| OPTION | AL: | |
|-----------------------------|----------------------------|----------------------|
| -Admission - Diagnosis - | Functiona Status | Payers |
| Admission Meds | General Status | Physical Exam |
| Advance Directive | History Past Illness | Procedures |
| Assessment & Plan | History Present Illness | Review of Systems |
| Course of Care | Immunizations | Social History |
| Discharge Diagnosis | Medical Equipment | |
| Encounters | Mental Status | |
| Family History | Nutrition | |

| REQUIRED: |
|--------------------------|
| Allergies & Intolerances |
| Medications |
| Problem |
| Procedures |
| Results |
| Social History |
| Vital Signs |
| |



Nutrition

HL7 C-CDA R2.1 – 70 Sections



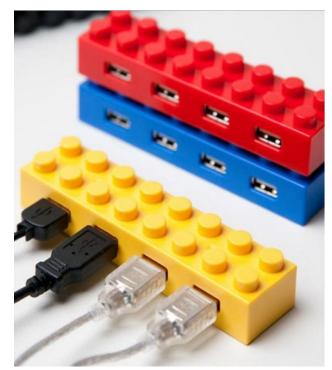
| | Admission Diagnosis | Admission Meds | Advance Directive | Allergies & Intolerances | Anesthesia | Assessment & Plan | |
|------------------------------|-------------------------------------|-------------------------|----------------------------|-----------------------------|---------------------------|------------------------------|-----------------------------|
| Assessment | Chief Complaint Reason for Visit | Chief Complaint | Complications | Course of Care | DICOM Object Catolog | Discharge Diagnosis | Discharge Diet |
| Discharge Medications | Encounters | Family History | Fetus Subject Context | Findings | Functional Status | General Status | Goals |
| Health Concerns | Health Status Eval/Outcomes | History Past Illness | History Present Illness | Hospital Consultations | Hospital Course | Hosp. Disch. Instructions | Hosp Disch. Physical |
| Hosp. Disch. Studies Sum. | Immunizations | | instructions | Interventions | Medical (Gen) History | Medical Equipment | Medications Administered |
| Medications | Mental Status | Nutrition | Objective | Observer Context | Operative Note Fluids | Op Note Surgical Proc. | Payers |
| Physical Exam | Plan of Treatment | Planned Procedure | Postoperative Diagnosis | Postprocedure Diagnosis | Preoperative Diagnosis | Problem | Procedure Description |
| Procedure Disposition | Procedure Est Blood Loss | Procedure Findings | Procedure Implants | Procedure Indications | Procedure Specimens | Procedures | Reason for Referral |
| Reason for Visit | Results | Review of Systems | Social History | Subjective | Surgery Description | Surgical Drains | Vital Signs |

Why is using the right type of document important?



- Each CDA Document is designed to address a specific purpose
 - Use Cases should be reviewed to determine appropriate documents for use to support optimal patient care
 - Documents need to fit the situation
 - Share information that is relevant and pertinent
- Establish the right context for the information being shared
 - Information about multiple encounters
 - Information about a single encounter
 - Information about a service(s) within an encounter
 - Information that is related to a specific order
 - Patient generated information vs. Clinician or System generated data

Incremental Improvements to Content Exchanged will lead to Improved Interoperability and Optimized Workflows







eHealth Exchange







Process for Creating Consistent & Robust HL7 C-CDAs



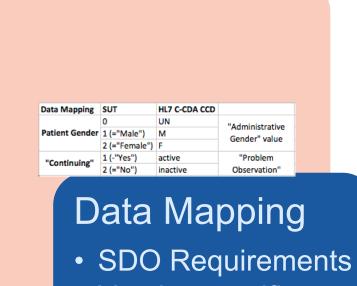
17



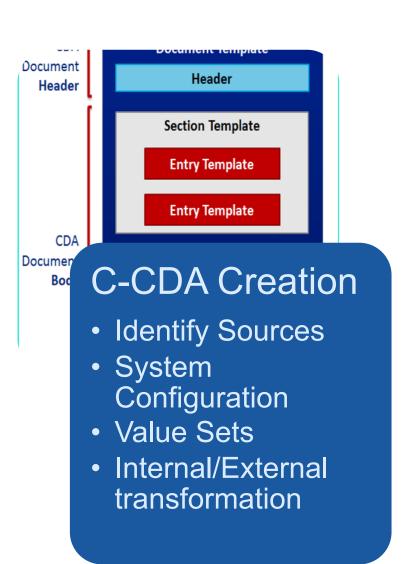
Clinicians

Others

Business Office



- Vendor specific data model overlay
- Semantic Interoperability Transformation



eHealth Exchange 2019 Annual Meeting Copyright © 2019 eHealth Exchange. All Rights Reserved.





18

- Email one question/issue/defect per email to testing@sequoiaproject.org
 - Provide as much information as possible including:
 - Screenshots
 - Testing Permanent Link with Issue
 - Reference details for specification questions/issues

Validate CDA documents



Screenshots of Issue Reporting Samples



19

```
4244
          <entryRelationship typeCode="COMP">
            <act classCode="ACT" moodCode="EVN">
4245
          \uparrow (14/221)
                                                  ccda212704
                        Test
                                                  /ClinicalDocument/component/structuredBody/component[8]/section/entry[1]/act/entryRelationship[0]/act
                        Location
                        Description
                                                  In Policy Activity (V3), the code of /hl7:act[hl7:templateId/@root='2.16.840.1.113883.10.20.22.4.61']/hl7:c
                                                  ode/hl7:translation SHALL be from the valueSet 2.16.840.1.114222.4.11.3591 (flexibility: 2018-08-27T0
                                                  0:00:00) (Item: CONF:1198-32852)[ Constraint... ] [ Assertion... ]
4246
              <templateId root="2.16.840.1.113883.10.20.22.4.61" />
4247
              <templateld root="2.16.840.1.113883.10.20.22.4.61" extension="2015-08-01" />
4248
              <id root="8A9522FA-0A08-2E1D-3E2A-E7BA679403B3" />
              <code code System="2.16.840.1.113883.3.88.12.3221.5.2" code SystemName="Health Insurance Type" code="C1" displayName="Commercial">
4249
                <originalText><reference value="#insuranceType-1"/></originalText>
4250
4251
                <translation co
4252
                  <originalText
4253
                </translation>
                                         a. This code SHALL contain at least one [1..*] translation, which SHOULD be selected
                                              from ValueSet Payer urn:oid:2.16.840.1.114222.4.11.3591 (CONF:1198-
                                              32852).
```

CONF: 1198-32852

In the validator the requirement to use that valueSet is a SHALL. In the HL7 R2.1 spec, the cited requirement is a SHOULD:





Please reference the Known Open Issues below before reporting tooling defects:

- 1. CONF: 81-7322 Improper Error being reported for Problem Status Value See Example below: In Problem Status, in /hl7:observation[hl7:templateId/@root='2.16.840.1.113883.10.20.22.4.6'], the element(s) hl7:value SHALL be from the datatype CE (Item: CONF:81-7322) Per June 2019 Errata published specifications the datatype should be CD and be labeled as CONF: 1198-7365.
- 2. CONF: 1198-32852 is a SHOULD and should only be generating a warning in the validator.
- 3. CONF:1098-7301 is a SHOULD and should only be generating a warning in the validator
- **4. CONF: 81-7291** The tooling is treating streetAddressLine like it has a cardinality of 1..1 when it should be 1..4 according to spec. If more than one streetAddressLine is in a document, no error should be firing.
- 5. **CONF: 1098-32478** is reporting as **SHALL** contain at least ONE hl7:author But the implementation guide says 0-* **SHOULD** for CONF: 1098-32478.

If your testing shows any of the above errors, please disregard at the present time until the validator can be rebuilt. These

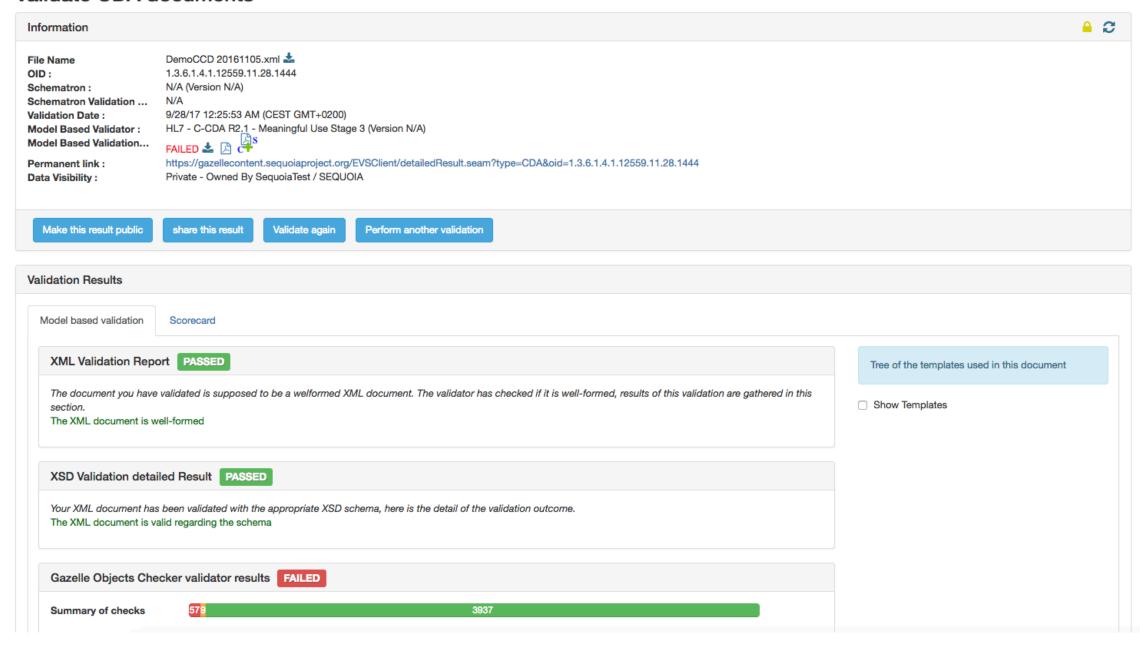
open issues are in the process of being remediated in the tooling and we will announce when updated.

Review Validation Report for Pass/Fail



21

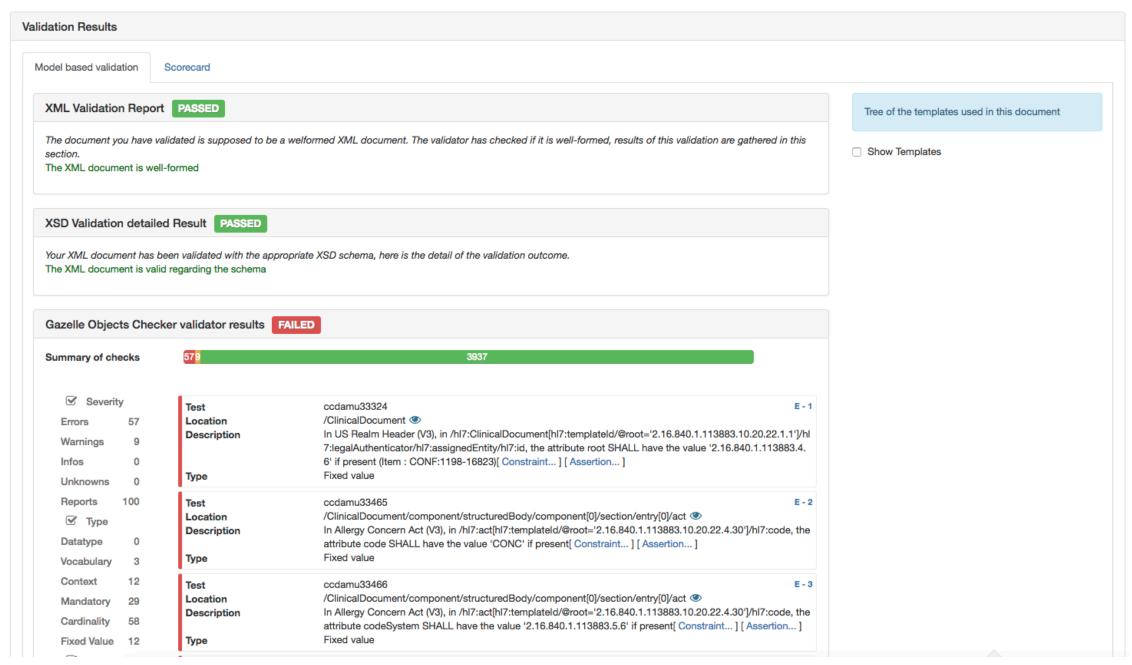
Validate CDA documents



Review Content Testing Validation Results Model based validation Tab



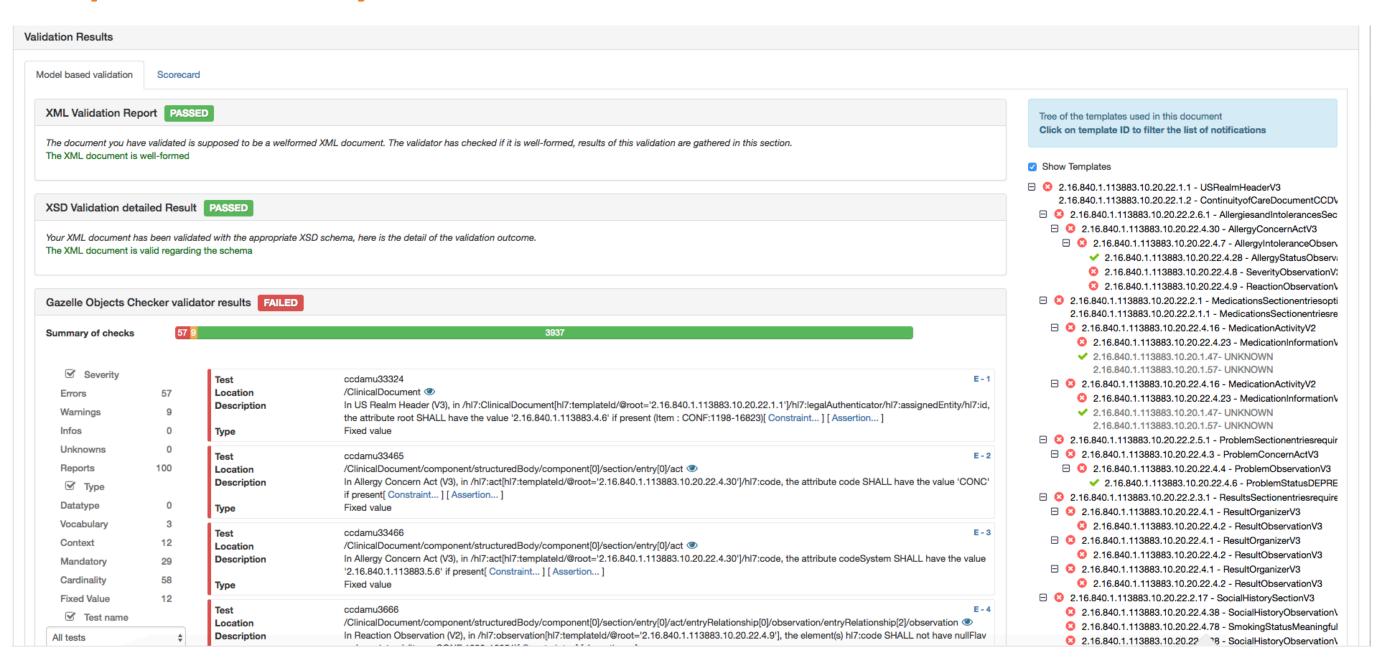
22



Template Summary Breakdown



23



Context Sensitive Drill Down

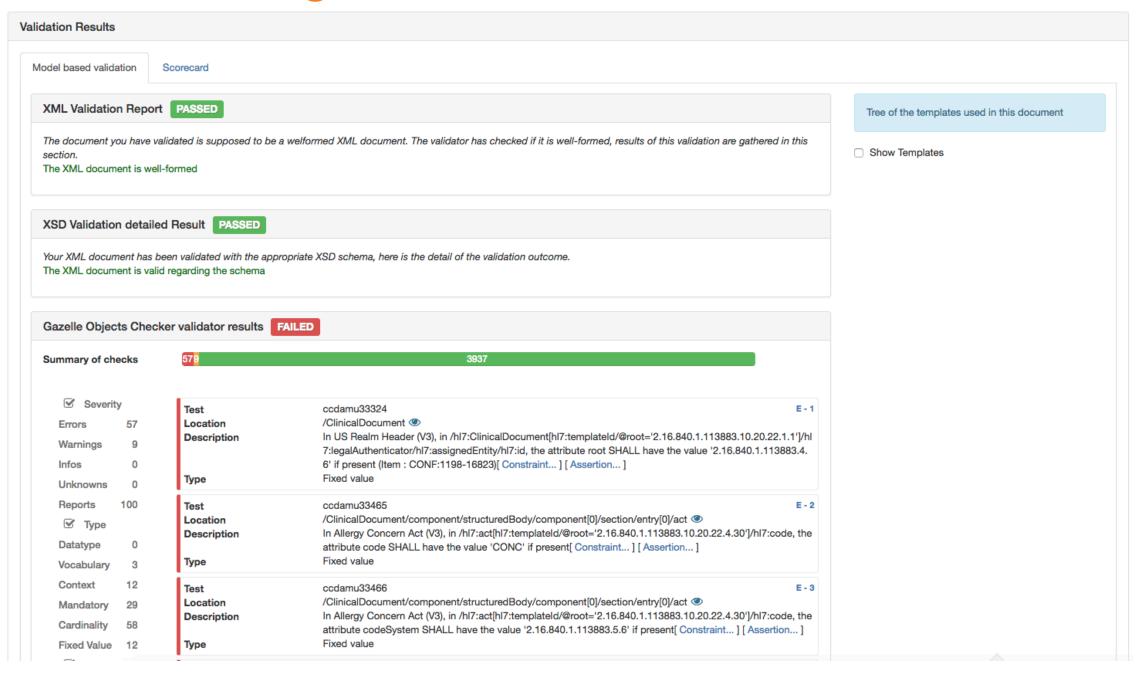


```
214
                      215
                        Codeine
                                                            Test
                                                                                              ccdamu33465
                                                                                                                                                                                                                 E - 2
                        Hives
216
                                                                                             /ClinicalDocument/component/structuredBody/component[0]/section/entry[0]/act @
217
                        Fatal
                                                            Location
218
                        Active
                                                                                             In Allergy Concern Act (V3), in /hl7:act[hl7:templateld/@root='2.16.840.1.113883.10.20.22.4.30']/hl7:code, the
                                                            Description
219
                      attribute code SHALL have the value 'CONC' if present[ Constraint... ] [ Assertion... ]
220
                    Fixed value
221
                                                            Type
                 222
                </text>
223
                <entry typeCode="DRIV">
224
                 <act classCode="ACT" moodCode="EVN">
          \uparrow (2/167)
                     Test
                                                ccdamu33465
                                                                                                                                    E-2
                      Location
                                                /ClinicalDocument/component/structuredBody/component[0]/section/entry[0]/act
                                                In Allergy Concern Act (V3), in /hl7:act[hl7:templateld/@root='2.16.840.1.113883.10.20.22.4.30']/hl7:code,
                      Description
                                                the attribute code SHALL have the value 'CONC' if present[ Constraint... ] [ Assertion... ]
225
                    <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
226
                    <!-- ** Allergy problem act ** -->
227
                    <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>
228
                    <code code="48765-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
229
                    <statusCode code="active"/>
230
                    <effectiveTime value="20090909">
                      <low value="20090902"/>
231
232
                      <high value="20100103"/>
233
                    </effectiveTime>
234
                    <entryRelationship typeCode="SUBJ">
235
                      <observation classCode="OBS" moodCode="EVN">
236
                        <!-- allergy observation template -->
237
                        <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
238
                        <id root="4adc1020-7b14-11db-9fe1-0800200c9a66"/>
239
                        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
240
                        <statusCode code="completed"/>
241
                        <effectiveTime>
242
                          <low value="20000215"/>
243
                        </effectiveTime>
244
                        <value xsi:type="CD" code="416098002" displayName="drug allergy" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
245
                        <participant typeCode="CSM">
```

Review Content Testing Validation Results – Scorecard tab



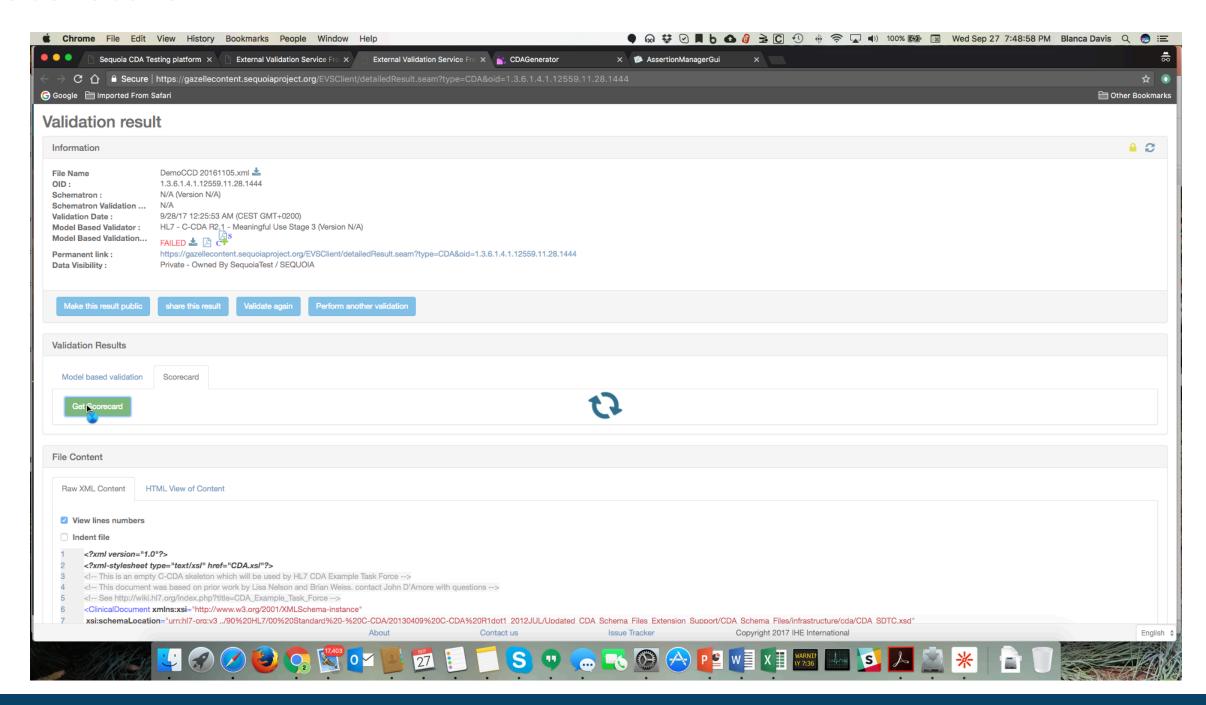
25



Get Scorecard

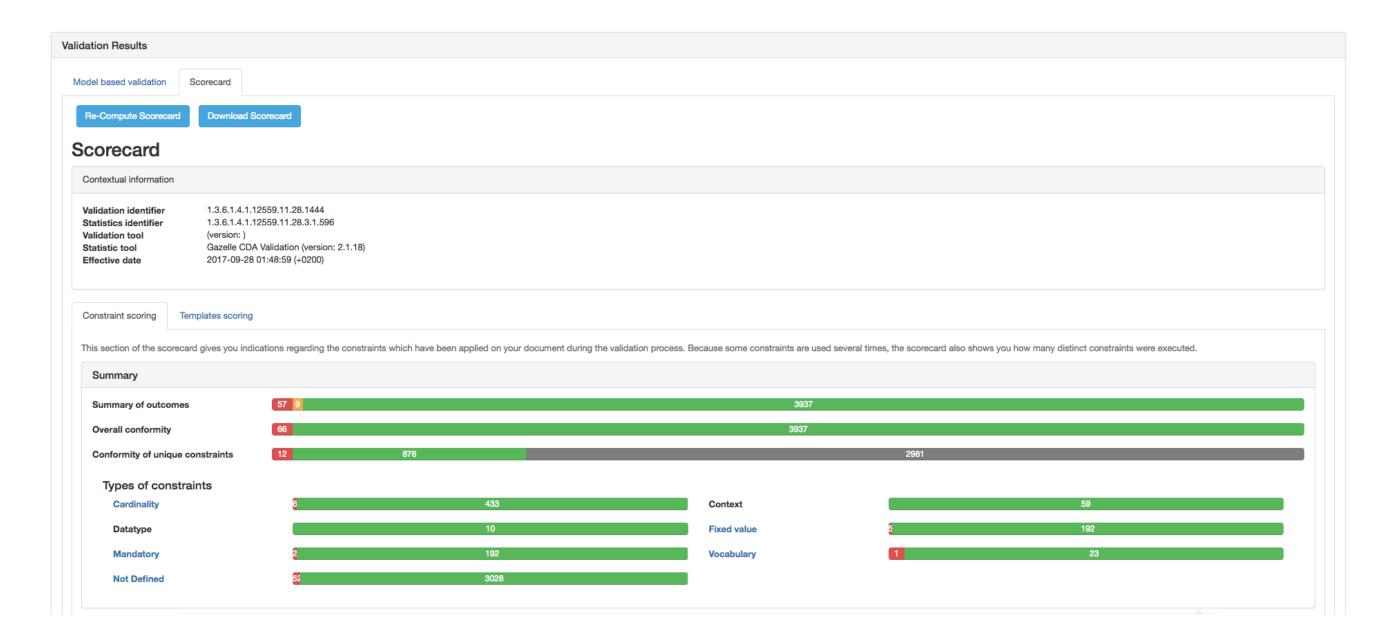
eHealth Exchange

26



Scorecard Report – Summary of Unique Issues





Scorecard Report – Detail of Unique Issues



28



XML Formatting Support for Readability



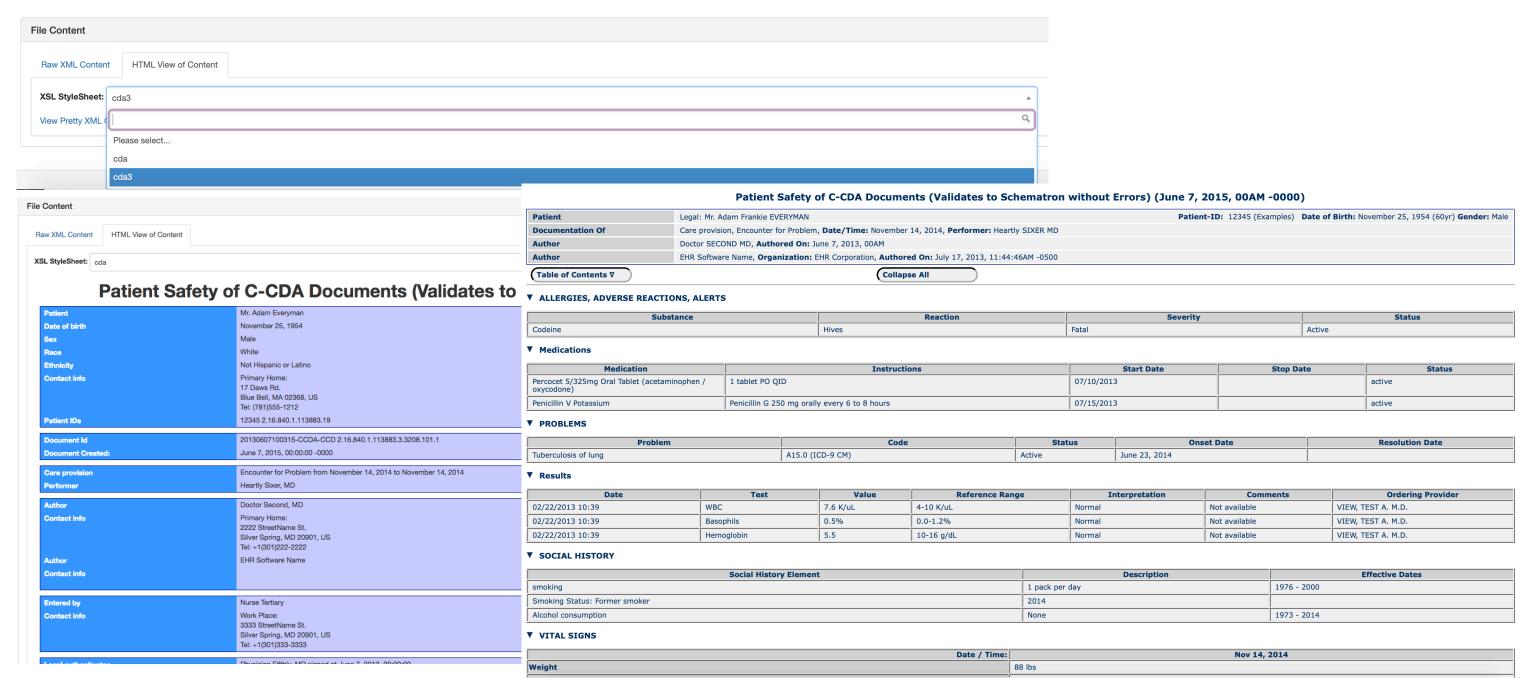
29

File Content File Content Raw XML Content HTML View of Content Raw XML Content **HTML View of Content** View lines numbers View lines numbers Indent file Indent file The following content has been modified (indented) for better visualization <?xml version="1.0" encoding="windows-1252" ?><ClinicalDocument xmlns="urn:hl7-org:v3"><realmCode code="US"</pre> <ClinicalDocument xmlns="urn:hl7-org:v3"> <templateld root="2.16.840.1.113883.10.20.22.1.1" /><templateld root="2.16.840.1.113883.10.20.22.1.1" extension="20"</p> <realmCode code="US"/> <id assigningAuthorityName="EPC" extension="548500a0-12b4-11ea-9cd3-00505686624a" root="1.2.840.114350.1.13" <typeld extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/> <templateId root="1.2.840.114350.1.72.1.51693"/> <id extension="SPR3099600" root="1.2.840.114350.1.13.445.3.7.3.68884.100" /><addr use="HP"><streetAddressLine> <templateId root="2.16.840.1.113883.10.20.22.1.1"/> <country>USA</country></addr><telecom use="HP" value="tel:+1-205-111-1111" /><patient><name use="L"><given>N <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01"/> <administrativeGenderCode code="M" codeSystem="2,16,840.1,113883.5,1" codeSystemName="AdministrativeGender <templateId root="2.16.840.1.113883.10.20.22.1.2"/> <maritalStatusCode code="S" codeSystem="2.16.840.1.113883.5.2" codeSystemName="MaritalStatusCode" displayNa</p> <templateld root="2.16.840.1.113883.10.20.22.1.2" extension="2015-08-01"/> 3" codeSystem="2.16.840.1.113883.6.238" codeSystemName="CDC Race and Ethnicity" displayName="White" /><ethi <id assigningAuthorityName="EPC" extension="548500a0-12b4-11ea-9cd3-00505686624a" root="1.2.840.114350.1.13.445.3.7.1.1"/> <a href="codeSystem="2.16.840.1.1138 <code code="34133-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Summarization of Episode Note"/> <id extension="75700" root="1.2.840.114350.1.13.445.3.7.2.688879" /><name>Spartanburg Regional Health Systems-TS <title>Clinical Summary</title> <city>SPARTANBURG</city><state>SC</state><postalCode>29303</postalCode><country>USA</country></addr> <effectiveTime value="20191129092710-0500"/> <addr nullFlavor="NA" /><telecom nullFlavor="NA" /><assignedAuthoringDevice><manufacturerModelName>Epic - Versi <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" displayName="Normal"/> <id extension="75700" root="1.2.840.114350.1.13.445.3.7.2.688879" /><name>Spartanburg Regional Health Systems-TS <languageCode code="en-US"/> <city>SPARTANBURG</city><state>SC</state><postalCode>29303</postalCode><country>USA</country></addr></rep <recordTarget> <id extension="75700" root="1.2.840.114350.1.13.445.3.7.2.688879" /><name>Spartanburg Regional Health Systems-TS <patientRole> <city>SPARTANBURG</city><state>SC</state><postalCode>29303</postalCode><country>USA</country></addr></re> <id extension="SPR3099600" root="1.2.840.114350.1.13.445.3.7.3.688884.100"/> <id extension="38070" root="1.2.840.114350.1.13.445.3.7.2.827665" /><code code="SPS" codeSystem="2.16.840.1.11 <telecom use="HP" value="tel:+1-864-560-6000" /><associatedPerson><name>Nwhinone Testpatient</name></associatedPerson><name>Nwhinone Testpatient</name><name>Nwhinone Testpatient</name></associatedPerson><name>Nwhinone Testpatient</name></associatedPerson><name>Nwhinone Testpati <streetAddressLine>1100 Test Street</streetAddressLine> <high value="20191129" /></effectiveTime><performer typeCode="PRF"><functionCode code="PCP" codeSystem="2.1" <county>JEFFERSON</county> <low value="20191107" /><high nullFlavor="PINF" /></time><assignedEntity><id extension="1306000948" root="2.16.8"</pre> <city>Helena</city> <originalText>Family Medicine/originalText></code><addr use="WP"><streetAddressLine>120 HEYWOOD AVENUE</streetAddressLine>120 HEYWOOD AVENUE <state>AL</state> <country>USA</country></addr><telecom use="WP" value="tel:+1-864-573-9595" /><telecom value="fax:+1-864-560-3"</pre> <postalCode>35080</postalCode> <representedOrganization classCode="ORG"><name>Spartanburg Regional Health Systems-TST</name><telecom nullF</pre> <country>USA</country> <state>SC</state><postalCode>29303</postalCode><country>USA</country></addr></representedOrganization></assignments <templateld root="2.16.840.1.113883.10.20.22.2.6" /><templateld root="2.16.840.1.113883.10.20.22.2.6" extension="20"</p> <telecom use="HP" value="tel:+1-205-111-1111"/> <id root="5488DB8A-12B4-11EA-9CD3-00505686624A" /><code code="48765-2" codeSystem="2.16.840.1.113883.6.1"</p> 27 <patient> <col span="2" width="25%" /><col width="13%" /><col width="12%" /><col width="25%" /></colgroup><thead> <name use="L"> PeanutID="allergy2reaction1">Rash</content>ID="allergy2severity">td><td ID="alle <given>Nwhinone</given> 30 <family>Nwhinzzztestpatient</family> <templateld root="2.16.840.1.113883.10.20.22.4.30" /><templateld root="2.16.840.1.113883.10.20.22.4.30" extension="6"</p> <statusCode code="active" /><effectiveTime><low value="20170811" /></effectiveTime><entryRelationship inversionInd</pre> <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1" codeSystemName="AdministrativeGenderCode" displayName="Male"/> <templateld root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" /><templateld root="2.16.840.1.113883.10.20.22.4.7"</p> 33 <birthTime value="19810101"/> <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" /><text><reference value="#allergy2" /></text><status</pre> 34 <sdtc:deceasedInd xmlns:sdtc="urn:hl7-org:sdtc" value="false"/> THE PROPERTY OF THE PROPERTY O

Stylesheet Display Support



30



Questions?

eHealth Exchange

https://ehealthexchange.org/testing-program/content-testing/